510(k) Summary for the

Family of disposable THD Anoscope, Proctoscope, Rectoscope and Light-scope

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

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Establishment Registration Number: 3006680097

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Summary Preparation Date: April 4, 2012

2.2. Names

Device Name: Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope

Classification Name: Endoscope and accessories

Product Code: FER/GCP

Regulation number: 876.1500

2.3. Predicate Devices

This 510(k) is related to the device modifications of the following devices:

Applicant	*Device name*	*510(k) Number*
THD S.p.A.	Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope	K103647

The Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope and its predicate device are indicated for the same intended use and have the same technological characteristics. Both families include the anoscopes, proctoscope the rectoscopes with the same dimensions and manufactured with the same process.

The differences between the families are that:

- The THD Light-scope devices are now available in sterile condition too.
- The handle material of the family is ABS Terluran and the cover of the integrated LED light source is ABS Novodur to replace in both cases ABS Lustran.

2.4. Device Description

The Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope are disposable, sterile or not sterile rectoscopes, proctoscope and anoscopes with a light source which can be external or integrated on the handle.
The devices are designed for the examination and treatment of anus (anoscopes) and the examination of rectum (proctoscopes and rectoscopes).
The devices consist of plastic anoscopes, proctoscope or rectoscopes for diagnostic or therapeutic use.
The Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope is made by two categories of devices:

- Diagnostic Anoscopes, Proctoscopes and Rectoscopes
- Surgical Proctoscopes

The Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope includes both models which require the external light source and models which not require the external light source. In the latter case the light source is integrated on the handle.
The external light source is provided as an accessory of the device family and it can be the THD Shining Light and the THD pen light. Both THD Shining Light and THD pen light have been already approved (K091490).

2.5. Indications for Use

The family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope is intended for physician use to examine the anal sphincter, anus, rectum

and to perform various diagnostic and therapeutic procedures by using additional accessories.

The Indications for Use of disposable Anoscope, Proctoscope, Rectoscope and Light-scope have not been modified with respect to the previous submission (K103647).

2.6. Design Control Activities

The risk analysis method used to assess the impact of the modifications is described in the Annex 4.3 - Risk management plan. The design verification tests were performed as a result of this risk analysis assessment (see Annex 4.2). The design verification tests are listed in the following table.

Modification	Test Performed	Acceptance Criteria
Sterility of the products	Validation and effectiveness test	Safety and effectiveness of sterilization method
Packaging	Design verification	Product shelf life maintenance
Handle materials	Design verification	Safety and effectiveness of the materials

A declaration of conformity with design controls is included in annex 1.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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THD S.p.a.
% Mr. Guido Bonapace, General Manager
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JUN - 1 2012

Re: K121135
Trade/Device Name: Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER, GCP
Dated: April 4, 2012
Received: April 13, 2012

Dear Mr. Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121135

Device Name: Family of disposable, sterile and not sterile THD Anoscope, Proctoscope, Rectoscope and Light-scope

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121135